

EXHIBIT B
PENDING CLAIMS
DIVISIONAL (4100.001482)

Claims 48-50, Group II:

48. A method of selecting an improved low molecular weight protamine species or fraction, comprising selecting from a plurality of low molecular weight protamine species or fractions a low molecular weight protamine species or fraction that substantially retains the bioactivity of native protamine and that has substantially reduced immunoresponsiveness or toxicity compared to native protamine.

49. The method of claim 48, wherein said plurality of low molecular weight protamine species or fractions are prepared by contacting a native protamine composition with at least a first proteolytic enzyme.

50. (Amended) The method of claim 48, further comprising formulating the improved low molecular weight protamine species or fraction selected in a pharmaceutically acceptable composition.

Claims 55-56 (and 59-63), Group III:

55. (Amended) A method of inactivating heparin or low molecular weight heparin, comprising contacting heparin or low molecular weight heparin with a biologically effective amount of at least a first purified bioactive protamine in accordance with claim 1.

56. The method of claim 55, wherein said heparin or low molecular weight heparin is located within a mammal and said composition is administered to said mammal.

Claim 57, Group IV:

57. (Amended) A method of ameliorating an effect of heparin or low molecular weight heparin in a mammal, comprising administering to said mammal a therapeutically effective amount of at least a first pharmaceutical composition comprising at least a first purified bioactive protamine in accordance with claim 1.

Claim 58, Group V:

58. (Amended) A method for treating or preventing undue or excessive bleeding in a mammal, comprising administering to a mammal having or at risk for developing excessive bleeding a therapeutically effective amount of at least a first pharmaceutical composition comprising at least a first purified bioactive protamine in accordance with claim 1.

Claims (55-56 and) 59-63, Group III:

59. (Amended) The method of claim 58, wherein said mammal exhibits excessive bleeding associated with systemic heparinization.

60. (Amended) The method of claim 58, wherein said mammal exhibits excessive bleeding associated with extracorporeal blood circulation.

61. (Amended) The method of claim 58, wherein said mammal exhibits excessive bleeding associated with a disease or disorder.

62. (Amended) The method of claim 58, wherein said mammal exhibits excessive bleeding associated with a trauma or surgery.

63. (Amended) The method of claim 58, wherein at least a second coagulant is further administered to said mammal.

Claims 64-68, Group VI:

64. (Amended) A method of prolonging the bioavailability of insulin upon administration to a mammal, comprising co-administering insulin to a mammal in combination with an effective amount of a protamine composition that comprises at least a first purified bioactive protamine in accordance with claim 1.

65. (Amended) A method for treating or preventing diabetes in a mammal, comprising administering insulin to a mammal having or at risk for developing diabetes in combination with a therapeutically effective amount of a protamine composition that comprises at least a first purified bioactive protamine in accordance with claim 1.

66. (Amended) The method of claim 64, wherein said insulin and said protamine composition are administered to said mammal in a single pharmaceutical composition.

67. (Amended) The method of claim 64, wherein said insulin and said protamine composition are administered to said mammal in distinct pharmaceutical compositions.

68. (Amended) The method of claim 56, wherein said mammal is a human subject.